DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9138-N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—

July through September 2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from April through June 2022, relating to the Medicare and Medicaid programs and other programs administered by CMS.

FOR FURTHER INFORMATION CONTACT: It is possible that an interested party may need specific information and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing contact persons to answer general questions concerning each of the addenda published in this notice.

Addenda	Contact	Phone Number
I CMS Manual Instructions	Ismael Torres	(410) 786-1864
II Regulation Documents Published in the Federal Register	Terri Plumb	(410) 786-4481
III CMS Rulings	Tiffany Lafferty	(410)786-7548
IV Medicare National Coverage Determinations	Wanda Belle, MPA	(410) 786-7491
V FDA-Approved Category B IDEs	John Manlove	(410) 786-6877
VI Collections of Information	William Parham	(410) 786-4669
VII Medicare –Approved Carotid Stent Facilities	Sarah Fulton, MHS	(410) 786-2749
VIII American College of Cardiology-National Cardiovascular Data Registry Sites	Sarah Fulton, MHS	(410) 786-2749
IX Medicare's Active Coverage-Related Guidance Documents	JoAnna Baldwin, MS	(410) 786-7205
X One-time Notices Regarding National Coverage Provisions	JoAnna Baldwin, MS	(410) 786-7205
XI National Oncologic Positron Emission Tomography Registry Sites	David Dolan, MBA	(410) 786-3365
XII Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities	David Dolan, MBA	(410) 786-3365
XIII Medicare-Approved Lung Volume Reduction Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XIV Medicare-Approved Bariatric Surgery Facilities	Sarah Fulton, MHS	(410) 786-2749
XV Fluorodeoxyglucose Positron Emission Tomography for Dementia Trials	David Dolan, MBA	(410) 786-3365
All Other Information	Annette Brewer	(410) 786-6580

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs and coordination and oversight of private health insurance.

Administration and oversight of these programs involves the following: (1) furnishing information to Medicare and Medicaid beneficiaries, health care providers, and the public; and (2) maintaining effective communications with CMS regional offices, state governments, state Medicaid agencies, state survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, National Association of Insurance Commissioners (NAIC), health insurers, and other stakeholders. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act) and Public Health Service Act. We also issue various manuals, memoranda, and statements necessary to administer and oversee the programs efficiently.

Section 1871(c) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides only the specific updates that have occurred in the 3-month period along with a hyperlink to the full listing that is available on the CMS website or the appropriate data registries that are used as our resources. This is the most current up-to-date information and will be available earlier than we publish our quarterly notice. We believe the website list provides more timely access for beneficiaries, providers, and suppliers. We also believe the website offers a more convenient tool for the public to find the full list of qualified providers for these specific services and offers more flexibility and "real time" accessibility. In addition, many of the websites have listservs; that is, the public can subscribe and receive immediate notification of any updates to the website. These listservs avoid the need to check the website, as notification of updates is automatic and sent to the subscriber as they occur. If assessing a website proves to be difficult, the contact person listed can provide information.

III. How to Use the Notice

This notice is organized into 15 addenda so that a reader may access the subjects

published during the quarter covered by the notice to determine whether any are of particular

interest. We expect this notice to be used in concert with previously published notices. Those

unfamiliar with a description of our Medicare manuals should view the manuals at

http://www.cms.gov/manuals.

The Director of the Office of Strategic Operations and Regulatory Affairs of the Centers

for Medicare & Medicaid Services (CMS), Kathleen Cantwell, having reviewed and approved

this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to

electronically sign this document for purposes of publication in the Federal Register.

Dated: November 4, 2022.

Trenesha Fultz-Mimms,

Federal Register Liaison, Department of

Health and Human Services.

Publication Dates for the Previous Four Quarterly Notices

We publish this notice at the end of each quarter reflecting information released by CMS during the previous quarter. The publication dates of the previous four Quarterly Listing of Program Issuances notices are: November 18, 2021 (86 FR 64492), February 9, 2022 (87 FR 7458), May 13, 2022 (87 FR 29327) and August 4, 2022 (87 FR 47751). We are providing only the specific updates that have occurred in the 3-month period along with a hyperlink to the website to access this information and a contact person for questions or additional information.

Addendum I: Medicare and Medicaid Manual Instructions (July through September 2022)

The CMS Manual System is used by CMS program components, partners, providers, contractors, Medicare Advantage organizations, and State Survey Agencies to administer CMS programs. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, guidelines, models, and directives. In 2003, we transformed the CMS Program Manuals into a web user-friendly presentation and renamed it the CMS Online Manual System.

How to Obtain Manuals

The Internet-only Manuals (IOMs) are a replica of the Agency's official record copy. Paper-based manuals are CMS manuals that were officially released in hardcopy. The majority of these manuals were transferred into the Internet-only manual (IOM) or retired. Pub 15-1, Pub 15-2 and Pub 45 are exceptions to this rule and are still active paper-based manuals. The remaining paper-based manuals are for reference purposes only. If you notice policy contained in the paper-based manuals that was not transferred to the IOM, send a message via the CMS Feedback tool.

Those wishing to subscribe to old versions of CMS manuals should contact the National Technical Information Service, Department of Commerce, 5301 Shawnee Road, Alexandria, VA 22312 Telephone (703-605-6050). You can download copies of the listed material free of charge at: http://cms.gov/manuals.

How to Review Transmittals or Program Memoranda

Those wishing to review transmittals and program memoranda can access this information at a local Federal Depository Library (FDL). Under the FDL program, government publications are sent to approximately 1,400 designated libraries throughout the United States. Some FDLs may have arrangements to transfer material to a local library not designated as an FDL. Contact any library to locate the nearest FDL. This information is available at http://www.gpo.gov/libraries/

In addition, individuals may contact regional depository libraries that receive and retain at least one copy of most federal government publications, either in printed or microfilm form, for use by the general

public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. CMS publication and transmittal numbers are shown in the listing entitled Medicare and Medicaid Manual Instructions. To help FDLs locate the materials, use the CMS publication and transmittal numbers. For example, to find the manual for Revision to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) to Align to 1834(a)(5)(E) of the Social Security Act (CMS-Pub. 100-03) Transmittal No. 11587.

Addendum I lists a unique CMS transmittal number for each instruction in our manuals or program memoranda and its subject number. A transmittal may consist of a single or multiple instruction(s). Often, it is necessary to use information in a transmittal in conjunction with information currently in the manual.

Fee-For Service Transmittal Numbers

Please Note: Beginning Friday, March 20, 2020, there will be the following change regarding the Advance Notice of Instructions due to a CMS internal process change. Fee-For Service Transmittal Numbers will no longer be determined by Publication. The Transmittal numbers will be issued by a single numerical sequence beginning with Transmittal Number 10000.

For the purposes of this quarterly notice, we list only the specific updates to the list of manual instructions that have occurred in the 3-month period. This information is available on our website at www.cms.gov/Manuals.

Transmittal Number	Manual/Subject/Publication Number				
Number	Medicare General Information (CMS-Pub. 100-01)				
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity				
	of Instructions				
11438	Issued to a specific audience, not posted to Internet/Intranet due to a				
	Confidentiality of Instruction				
	Medicare Benefit Policy (CMS-Pub. 100-02)				
11501	Issued to a specific audience, not posted to Internet/Intranet due to a				
	Confidentiality of Instruction				
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity				
	of Instructions				
N	Iedicare National Coverage Determination (CMS-Pub. 100-03)				
11587	Revision to National Coverage Determination (NCD) 240.2 (Home Use of				
	Oxygen) to Align to 1834(a)(5)(E) of the Social Security Act				
	Medicare Claims Processing (CMS-Pub. 100-04)				
11484	Issued to a specific audience, not posted to Internet/Intranet due to a				
	Confidentiality of Instruction				
11486	Issued to a specific audience, not posted to Internet/Intranet due to a				
	Confidentiality of Instruction				
11487	Issued to a specific audience, not posted to Internet/Intranet due to a				
	Confidentiality of Instruction				

11490	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11493	Claim Status Category and Claim Status Codes Update
11494	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
	of Instructions
11496	October 2022 Quarterly Average Sales Price (ASP) Medicare Part B Drug
	Pricing Files and Revisions to Prior Quarterly Pricing Files
11497	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11498	Issued to a specific audience, not posted to Internet/Intranet due to a
11500	Confidentiality of Instruction
11500	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11502	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
11302	of Instructions
11504	Modification of Existing Common Working File (CWF) Editing for
	Preventive Services
11507	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11508	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11509	Cessation of Use of MyMedicare.gov Web Address
11510	Masking the Medicare Beneficiary Identifier (MBI) on the Medicare
	Summary Notice (MSN)
11511	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11514	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11518	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
11010	of Instructions
11519	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
11017	of Instructions
11520	Issued to a specific audience, not posted to Internet/Intranet due to Sensitivity
	of Instructions
11523	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11527	Issued to a specific audience, not posted to Internet/Intranet due to a
11027	Confidentiality of Instruction
11531	Issued to a specific audience, not posted to Internet/Intranet due to a
11001	Confidentiality of Instruction
11532	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11540	Inpatient Rehabilitation Facility (IRF) Annual Update: Prospective Payment
115-10	System (PPS) Pricer Changes for FY 2023
11541	Medicare Part A Skilled Nursing Facility (SNF) Prospective Payment System
115-11	(PPS) Pricer Update Fiscal Year (FY) 2023
11542	Update to Hospice Payment Rates, Hospice Cap, Hospice Wage Index and
11372	Hospice Pricer for Fiscal Year (FY) 2023
11543	Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)
11343	Updates for Fiscal Year (FY) 2023
11544	Quarterly Update to the Medicare Physician Fee Schedule Database
11377	(MPFSDB) - October 2022 Update
11547	New Waived Tests
11547	
11348	Issued to a specific audience, not posted to Internet/Intranet due to a Confidentiality of Instruction
11549	Remittance Advice Remark Code (RARC), Claims Adjustment Reason Code
115-17	(CARC), Medicare Remit Easy Print (MREP) and PC Print Update
	(Critic), Wiedicare Reinit Easy 1 thit (WIRE) and 1 C 1 thit Opdate

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	Procedure-to-Procedure (PTP) Edits, Version 29.0, Effective January 2023
11600	Instructions for Retrieving the January 2023 Opioid Treatment Program
	(OTP) Payment Rates Through the CMS Mainframe Telecommunications
	System
11601	Annual Update of Healthcare Common Procedure Coding System (HCPCS)
	Codes Used for Home Health Consolidated Billing Enforcement
11602	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11603	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11604	Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and
11.50	Laboratory Services Subject to Reasonable Charge Payment
11605	Issued to a specific audience, not posted to Internet/Intranet due to a
11610	Confidentiality of Instruction
11610	October 2022 Update of the Ambulatory Surgical Center (ASC) Payment
11611	System L 2022 O 4 1 A 5 G 1 B 1 (ASB) M 11 B 4 B B
11611	January 2023 Quarterly Average Sales Price (ASP) Medicare Part B Drug
11612	Pricing Files and Revisions to Prior Quarterly Pricing Files
11012	Quarterly Update for the Durable Medical Equipment, Prosthetics, Orthotics, and Symplics (DMEROS) Competitive Pidding Program (CPR), January
	and Supplies (DMEPOS) Competitive Bidding Program (CBP) - January 2023
11617	Instructions for Retrieving the January 2023 Home Infusion Therapy (HIT)
1101/	Services Payment Rates Through the CMS Mainframe Telecommunications
	System
11618	Instructions for Downloading the Medicare ZIP Code File for January 2023
11619	October Quarterly Update for 2022 Durable Medical Equipment, Prosthetics,
11019	Orthotics and Supplies (DMEPOS) Fee Schedule
11620	Issued to a specific audience, not posted to Internet/Intranet due to a
11020	Confidentiality of Instruction
11621	Issued to a specific audience, not posted to Internet/Intranet due to a
11021	Confidentiality of Instruction
	Medicare Secondary Payer (CMS-Pub. 100-05)
11512	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11513	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11550	Significant Updates to Internet Only Manual (IOM) Publication (Pub.) 100-05
	Medicare Secondary Payer (MSP) Manual, Chapter 5
11557	Automation of the Medicare Duplicate Primary Payment (DPP) Process
	Medicare Financial Management (CMS-Pub. 100-06)
11495	Automation of the Duplicate Primary Payer (DPP) Process
11499	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files
	to the Provider and Statistical Reimbursement (PS&R) System
11562	The Fiscal Intermediary Shared System (FISS) Submission of Copybook Files
	to the Provider and Statistical Reimbursement (PS&R) System
207	Medicare State Operations Manual (CMS-Pub. 100-07)
207	Revisions to State Operation Manual (SOM), Appendix PP Guidance to
	Surveyors for Long Term Care Facilities
11400	Medicare Program Integrity (CMS-Pub. 100-08)
11480	Issued to a specific audience, not posted to Internet/Intranet due to a
11/02	Confidentiality of Instruction
11483	Issued to a specific audience, not posted to Internet/Intranet due to a
11528	Confidentiality of Instruction Issued to a specific audience, not posted to Internet/Intranet due to a
11328	Confidentiality of Instruction
	Confidentiality of histraction

11.500	Type of the second seco
11529	Update of Chapter 3 in Publication (Pub.) 100-08, Including Update to
	Medicare Program Integrity Contractor Post-Payment Review Process, and
	Update of Chapter 8 Pub. 100-08, Including Revision to When Contractor
	Suspects Additional Improper Claims Medical Record Review Contractor
	Suspects Additional Improper Claims
11530	Issued to a specific audience, not posted to Internet/Intranet due to a
	Confidentiality of Instruction
11536	Provider/Supplier Enrollment Adverse Legal Actions
11537	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11556	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11563	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11574	Sixth General Update to Provider Enrollment Instructions in Chapter 10 of
	Publication (Pub.) 100-08, Program Integrity Manual (PIM)
11575	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11576	Final Round of Transition of Enrollment and Certification Activities for
	Various Certified Provider and Supplier Types and Transactions
11580	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11588	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11597	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11598	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11606	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11608	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11609	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11613	Final Round of Transition of Enrollment and Certification Activities for
	Various Certified Provider and Supplier Types and Transactions
	Contractor Beneficiary and Provider Communications (CMS-Pub. 100-09)
11579	Issued to a specific audience, not posted to Internet/Intranet due to
	Confidentiality of Instructions
11616	The Supplemental Security Income (SSI)/Medicare Beneficiary Data for
	Fiscal Years (FYs) 2019 and 2020 for Inpatient Prospective Payment System
	(IPPS) Hospitals with Updated Data for Hospitals in the 9th Circuit
M	edicare Quality Improvement Organization (CMS- Pub. 100-10)
	None
Medicar	re End Stage Renal Disease Network Organizations (CMS Pub 100-14)
	None
Medic	aid Program Integrity Disease Network Organizations (CMS Pub 100-15)
	None
	Medicare Managed Care (CMS-Pub. 100-16)
	None
	ledicare Business Partners Systems Security (CMS-Pub. 100-17)
11570	Pub 100-17 Medicare Business Partners Systems Security Manual Update

	Medicare Prescription Drug Benefit (CMS-Pub. 100-18)
	None
	Demonstrations (CMS-Pub. 100-19)
11489	ESRD Treatment Choices (ETC) Model Performance Payment Adjustment (PPA) - Facility Component (Implementation CR)
11505	Concatenation of Multiple Separate Comma-Separated Values Files to One File - Update to CR 12492 – Implementation
11506	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11515	Federally Qualified Health Center (FQHC) Participation in and Payment Under the Maryland Primary Care Program (MDPCP) - Implementation Change Request (CR) to correct Business Requirement (BR) 12326.7.2.
11516	Monthly Report of Performance Payment Adjustment (PPA) Claims - Addition to Change Request (CR) 12404 - Implementation CR
11517	Remove Beneficiaries Below 18 Years Old From Model Adjustments – Correction for CR11390
11534	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11553	Automatic Reprocessing of Claims for Kidney Care Choices (KCC) Model- Implementation
11554	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
	One Time Notification (CMS-Pub. 100-20)
11481	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11482	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction
11485	Instructions to the Fiscal Intermediary Shared System [FISS] Edit to Expand the Existing MA Bypass Reusable Solution PARMCC78 and Modify the Existing Logic to Read the New PARMs
11488	New Edit for Prospective Payment System (PPS) Outpatient and Inpatient Bill Types Receiving an Outlier Payment When a Device Credit is Reported
11491	Interns and Residents Information System (IRIS) XML Format
11492	User CR: MCS - HIMR Functions Menu Additional Fields
11503	Corrections to Processing of Canceled Home Health Notices of Admission and of Period Sequence Edits
11521	Multi-Carrier System (MCS) Removal of the Physician Pay for Reporting (P4R), Physician Quality Reporting System (PQRS) and Electronic Prescribing (ERx) Incentive Payments Financial Logic from the Claims Processing System
11522	Remove Hard Coded Logic for Edits 004H and 005H - Remove the Edits from Displaying on the H99RBEA1 and H99RBEA2 Reports
11524	Issued to a specific audience, not posted to Internet/Intranet due to Confidentiality of Instructions
11525	User Enhancement Change Request (CR) - Update the Multi-Carrier System (MCS) Desk Top Tool (MCSDT) Editing for Same Day Adjustments
11526	User Enhancement Change Request (CR)- Update the Model Participant Provider (M1) Screen and Model Participant Provider Report (H99RVMPP) in the Multi-Carrier System (MCS)
11533	Implementation of the Capital Related Assets Adjustment (CRA) for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Under the End Stage Renal Disease Prospective Payment System (ESRD PPS)
11535	Health Insurance Portability and Accountability Act (HIPAA) Electronic Data Interchange (EDI) Front-End Updates for January 2023
11538	Issued to a specific audience, not posted to Internet/Intranet due to a Sensitivity of Instruction

11539	Implementation of the Award for the Jurisdiction N (J-N) Part A and Part B
11339	Medicare Administrative Contractor (JN A/B MAC)
11545	International Classification of Diseases, 10th Revision (ICD-10) and Other
11343	Coding Revisions to National Coverage Determination (NCDs)January
	2023 Update
11546	The purpose of this Change Request (CR) is to provide a maintenance update
	of ICD-10 conversions and other coding updates specific to NCDs. These
	NCD coding changes are the result of newly available codes, coding revisions
	to NCDs released separately, or coding feedback received. Previous NCD
	coding changes appear in ICD-10 quarterly updates that can be found at:
	https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/ICD10.html,
	along with other CRs implementing new policy NCDs
11568	User CR: MCS - HIMR Functions Menu Additional Fields
11569	Medicare Summary Notice (MSN) Created with Wrong Beneficiary Data -
	Update Beneficiary Data Streamlining Logic
11577	Issued to a specific audience, not posted to Internet/Intranet due to
11570	Confidentiality of Instructions
11578	Updated Merit-based Incentive Payment System (MIPS)/MIPS Value Pathways (MVP) Healthcare Common Procedure Coding System (HCPCS)
	Codes
11582	Mobile Personal Identity Verification (PIV) Station
11584	International Classification of Diseases, 10th Revision (ICD-10) and Other
11304	Coding Revisions to National Coverage Determination (NCDs)January
	2023 Update
11585	User Enhancement Change Request (CR) - Update the Multi-Carrier System
	(MCS) Desk Top Tool (MCSDT) Editing for Same Day Adjustments
11586	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11607	Issued to a specific audience, not posted to Internet/Intranet due to a
	Sensitivity of Instruction
11614	Issued to a specific audience, not posted to Internet/Intranet due to a
11(22	Sensitivity of Instruction
11622	Changes to Beneficiary Coinsurance for Additional Procedures Furnished During the Same Clinical Encounter As Certain Colorectal Cancer Screening
	Tests
11623	Updates to the Common Working File (CWF) for Editing and Claims
11023	Processing to Allow Medicare Fee-For-Service (FFS) Coverage of Kidney
	Acquisition Costs for Medicare Advantage (MA) Beneficiaries Provided by
	Maryland Waiver (MW) Hospitals
Me	edicare Quality Reporting Incentive Programs (CMS- Pub. 100-22)
	None
	State Payment of Medicare Premiums (CMS-Pub.100-24)
	None None
Inf	Formation Security Acceptable Risk Safeguards (CMS-Pub. 100-25)
	None

Addendum II: Regulation Documents Published in the Federal Register (July through September 2022)

Regulations and Notices

Regulations and notices are published in the daily Federal Register. To purchase individual copies or subscribe to the Federal Register, contact GPO at www.gpo.gov/fdsys. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

The **Federal Register** is available as an online database through GPO Access. The online database is updated by 6 a.m. each day the **Federal Register** is published. The database includes both text and graphics from Volume 59, Number 1 (January 2, 1994) through the present date and can be accessed at http://www.gpoaccess.gov/fr/index.html. The following website http://www.archives.gov/federal-register/ provides information on how to access electronic editions, printed editions, and reference copies.

This information is available on our website at: https://www.cms.gov/files/document/regs3q22qpu.pdf

For questions or additional information, contact Terri Plumb (410-786-4481).

Addendum III: CMS Rulings (July through September 2022)

CMS Rulings are decisions of the Administrator that serve as precedent final opinions and orders and statements of policy and interpretation. They provide clarification and interpretation of complex or ambiguous provisions of the law or regulations relating to Medicare, Medicaid, Utilization and Quality Control Peer Review, private health insurance, and related matters.

The rulings can be accessed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings. For questions or additional information, contact Tiffany Lafferty (410-786-7548).

Addendum IV: Medicare National Coverage Determinations (July through September 2022)

Addendum IV includes completed national coverage determinations (NCDs), or reconsiderations of completed NCDs, from the quarter covered by this notice. Completed decisions are identified by the section of the NCD Manual (NCDM) in which the decision appears, the title, the date the publication was issued, and the effective date of the decision. An NCD is a determination by the Secretary for whether or not a particular item or service is covered nationally under the Medicare Program (title XVIII of the Act), but does not include a determination of the code, if any, that is assigned to a particular covered item or service, or payment determination for a particular covered item or service. The entries below include information concerning completed decisions, as well as sections on program and decision memoranda, which also announce decisions or, in some cases, explain why it was not appropriate to issue an NCD. Information on completed decisions as well as pending decisions has also been posted on the CMS website. There are no updates to national coverage determinations (NCDs), or reconsiderations of completed NCDs published in the 3-month period. This information is available at:

www.cms.gov/medicare-coverage-database/. For questions or additional information, contact Wanda Belle, MPA (410-786-7491).

Addendum V: FDA-Approved Category B Investigational Device Exemptions (IDEs) (July through September 2022)

(Inclusion of this addenda is under discussion internally.)

Addendum VI: Approval Numbers for Collections of Information (July through September 2022)

All approval numbers are available to the public at Reginfo.gov. Under the review process, approved information collection requests are assigned OMB control numbers. A single control number may apply to several related information collections. This information is available at www.reginfo.gov/public/do/PRAMain. For questions or additional information, contact William Parham (410-786-4669).

Addendum VII: Medicare-Approved Carotid Stent Facilities (July through September 2022)

Addendum VII includes listings of Medicare-approved carotid stent facilities. All facilities listed meet CMS standards for performing carotid artery stenting for high risk patients. On March 17, 2005, we issued our decision memorandum on carotid artery stenting. We determined that carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. We have created a list of minimum standards for facilities modeled in part on professional society statements on competency. All facilities must at least meet our standards in order to receive coverage for carotid artery stenting for high risk patients. For the purposes of this quarterly notice, we are providing only the specific updates that have occurred in the 3-month period. This information is available at: http://www.cms.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider	Date	State
	Number	Approved	
The following facilities a	re new listings fo	r this quarter.	
Medical City Alliance	670103	05/01/2022	TX
3101 N. Tarrant Parkway			
Fort Worth, TX 76177			
South Baldwin Regional Medical	010083	07/07/2022	AL
1613 N. McKenzie Street			
Foley, AL 36535			
Ogden Regional Medical Center	1720031636	07/15/2022	UT
5475 South 500			
Ogden, UT 844505			
Cleveland Clinic Tradition Hospital	100044	07/26/2022	FL

Facility	Provider Number	Date Approved	State
10000 SW Innovation Way			
Port St. Lucie, FL 34987			
Cleveland Clinic Martin North Hospital	100044	07/26/2022	FL
200 SE Hospital Avenue			
Stuart, FL 34994			
Aurora St. Luke's Medical Center	520138	07/09/2022	WI
2900 West Oklahoma Avenue			
Milwaukee, WI 53215			
HCA Florida Gulf Coast Hospital	1548392475	08/16/2022	FL
449 W. 23rd Street			
Panama City, FL 32405			
Decatur Morgan Hospital	010085	09/20/2022	AL
1201 7th Street			
Decatur, AL 35601			
Centennial Hills Hospital Medical	290054	09/27/2022	NV
Center			
6900 N. Durango Drive			
Las Vegas, NV 89149			
Indiana Regional Medical Center	390173	10/25/2022	PA
835 Hospital Road			
Indiana, PA 15701			
Stillwater Medical Center Authority	370049	10/25/2022	OK
1323 W. 6th Avenue			
Stillwater, OK 74074			
Memorial Hermann Sugar Land	1295788735	10/25/2022	TX
Hospital			
17500 W Grand Parkway S			
Sugar Land, TX 77479			
Hilo Medical Center	120005	10/25/2022	HI
1190 Waianuenue Avenue			
Hilo, HI 96720			
The following facilities			L
FROM: Blake Medical Center	114964244	11/06/2008	FL
TO: HCA Florida Blake Hospital			
2020 59th Street W			
Bradenton, FL 34209	100005	0.5/22/2005	FI
FROM: Orlando Health	100006	05/23/2005	FL
TO: OH Orlando Regional Medical			
Center			
1414 Kuhl Avenue			
Orlando FL 32806	150162	00/20/2006	- DI
FROM: St. Francis Hospital and	150162	08/28/2006	IN
Health Centers – Indianapolis			
TO: Franciscan Health Indianapolis			
8111 South Emerson Avenue			
Indianapolis, IN 46237			

Facility	Provider	Date	State
	Number	Approved	
FROM: Great River Medical Center	420680407	04/16/2010	IA
TO: Southeast Iowa Regional			
Medical Center			
1221 S. Gear Avenue			
West Burlington, IA 52655-1681			
The following fa	cility is being ren	noved.	
Franciscan St. Francis Health –	150033	04/01/2005	IN
Indianapolis			
1600 Albany Street			
Beech Grove, IN 46107			

Addendum VIII:

American College of Cardiology's National Cardiovascular Data Registry Sites (July through September 2022)

The initial data collection requirement through the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) has served to develop and improve the evidence base for the use of ICDs in certain Medicare beneficiaries. The data collection requirement ended with the posting of the final decision memo for Implantable Cardioverter Defibrillators on February 15, 2018.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum IX: Active CMS Coverage-Related Guidance Documents (July through September 2022)

CMS issued a guidance document on November 20, 2014 titled "Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development Document". Although CMS has several policy vehicles relating to evidence development activities including the investigational device exemption (IDE), the clinical trial policy, national coverage determinations and local coverage determinations, this guidance document is principally intended to help the public understand CMS's implementation of coverage with evidence development (CED) through the national coverage determination process. The document is available at http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27. There are no additional Active CMS Coverage-Related Guidance Documents for the 3-month period. For questions or additional information, contact JoAnna Baldwin, MS (410-786-7205).

Addendum X:

List of Special One-Time Notices Regarding National Coverage Provisions (July through September 2022)

There were no special one-time notices regarding national coverage provisions published in the 3-month period. This information is available at http://www.cms.gov . For questions or additional information, contact JoAnna Baldwin, MS (410-786 7205).

Addendum XI: National Oncologic PET Registry (NOPR) (July through September 2022)

Addendum XI includes a listing of National Oncologic Positron Emission Tomography Registry (NOPR) sites. We cover positron emission tomography (PET) scans for particular oncologic indications when they are performed in a facility that participates in the NOPR.

In January 2005, we issued our decision memorandum on **positron emission tomography** (PET) scans, which stated that CMS would cover PET scans for particular oncologic indications, as long as they were performed in the context of a clinical study. We have since recognized the National Oncologic PET Registry as one of these clinical studies. Therefore, in order for a beneficiary to receive a Medicare-covered PET scan, the beneficiary must receive the scan in a facility that participates in the registry. There were no additions, deletions, or editorial changes to the listing of National Oncologic Positron Emission Tomography Registry (NOPR) in the 3-month period. This information is available at http://www.cms.gov/MedicareApprovedFacilitie/NOPR/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

Addendum XII: Medicare-Approved Ventricular Assist Device (Destination Therapy) Facilities (July through September 2022)

Addendum XII includes a listing of Medicare-approved facilities that receive coverage for ventricular assist devices (VADs) used as destination therapy. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy. On October 1, 2003, we issued our decision memorandum on VADs for the clinical indication of destination therapy. We determined that VADs used as destination therapy are reasonable and necessary only if performed in facilities that have been determined to have the experience and infrastructure to ensure optimal patient outcomes. We established facility standards and an application process. All facilities were required to meet our standards in order to receive coverage for VADs implanted as destination therapy.

For the purposes of this quarterly notice, we are providing only the specific updates to the list of Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at

http://www.cms.gov/MedicareApprovedFacilitie/VAD/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA, (410-786-3365).

Facility	Provider Number		Date of Re- certification	State	
The following facilities have editorial changes (in bold).					

Westchester Health Care Corporation 100 Woods Road	330234	11/29/2009	06/30/2022	NY
Valhalla, NY 10595				
Other information: Joint Commission ID # 2518				
Previous Re-certification Dates: 11/19/2009;				
11/15/2011; 12/03/2013; 12/08/2015; 12/19/2017; 03/07/2020				
Ronald Reagan UCLA Medical Center	050262	02/06/2009	04/09/2022	CA
757 Westwood Plaza Los Angeles, CA 90095				
Other information: Joint Commission ID # 9944				
Previous Re-certification Dates: 02/06/2009;				
08/09/2011; 08/13/2013; 09/15/2015; 10/06/2017; 12/04/2019				
St. Vincent Infirmary Medical Center dba CHI St. Vincent	040007	11/21/2017	05/04/2022	AR
2 St. Vincent Circle Little Rock, AR 72205				
Other information: Joint Commission ID # 8661				
Previous Re-certification Dates: 11/21/2017; 02/05/2020				
Lancaster General Hospital 555 North Duke Street Lancaster, PA 17602	390100	05/19/2009	05/04/2022	PA
Other information: Joint Commission ID # 6086				
Previous Re-certification Dates: 05/19/2009;				
09/23/2011; 09/06/2013; 09/22/2015; 10/03/2017; 02/05/2020				
University of Kentucky Hospital/ UK Albert B. Chandler Hospital	180067	02/10/2009	05/12/2022	KY
800 Rose Street Lexington, KY 40536-0293				
Other information: Joint Commission ID # 7760				

Previous Re-certification Dates: 02/10/2009; 09/20/2011; 09/18/2013;				
11/03/2015; 12/05/2017; 02/26/2020				
Lehigh Valley Hospital 1200 S. Cedar Crest Boulevard Allentown, PA 18105	390133	10/29/2013	05/28/2022	PA
Other information: Joint Commission ID # 4880				
Previous Re-certification Dates: 10/29/2013; 11/10/2015; 12/12/2017; 03/04/2020				
UMC Health System 602 Indiana Avenue Lubbock, TX 79415	450686	06/17/2017	07/26/2022	TX
DNV Healthcare Certificate #: C558801				
Previous Re-certification Dates: 06/17/2017; 06/09/2019				
West Penn Allegheny Health System, Inc. 320 East North Avenue Pittsburgh, PA 15212	390050	03/07/2008	07/27/2022	PA
Other information: Joint Commission ID # 6158				
Previous Re-certification Dates: 03/07/2008; 04/02/2010; 03/13/2012; 02/11/2014; 03/15/2016; 03/30/2018; 01/09/2021				
University of Michigan Health System 1500 E Medical Center Drive, SPC 5474 Ann Arbor, MI 48109	230046	03/27/2008	06/03/2022	MI
Other information: Joint Commission ID # 7457				
Previous Re-certification Dates: 03/27/2008; 03/18/2010; 03/07/2012; 02/04/2014; 03/15/2016; 04/24/2018; 12/03/2020				
Baptist Health Medical Center - Little Rock 9601 Baptist Health Drive Little Rock, AR 72205-7299	040114	11/10/2009	05/07/2022	AR

			1	
Other information:				
Joint Commission ID # 8656				
Previous Re-certification				
Dates: 11/10/2009;				
11/08/2011; 12/11/2013;				
01/12/2016; 12/15/2017;				
02/12/2020				
Sutter Medical Center	050108	10/20/2009	06/16/2022	CA
2825 Capitol Ave				
Sacramento, CA 95816				
Other information:				
Joint Commission ID # 2902				
Previous Re-certification				
Dates: 10/20/2009;				
09/22/2011; 10/17/2013;				
10/27/2015; 11/07/2017;	1			
03/04/2020				
WellSpan York Hospital	390046	11/19/2012	06/18/2022	PA
1001 South George Street	1			
York, PA 17405	1			
	1			
Other information:				
Joint Commission ID # 6228				
Previous Re-certification				
Dates:				
11/19/2013; 12/15/2015;				
01/23/2018; 03/14/2020				
UPMC Presbyterian Shadyside	390164	06/10/2008	06/03/2022	PA
200 Lothrop Street				
Pittsburgh, PA 15213				
	1			
Other information:	1			
Joint Commission ID # 6169	1			
	1			
Previous Re-certification	1			
Dates: 06/10/2008;				
05/21/2010; 04/12/2012;	1			
03/25/2014; 04/13/2016;	1			
03/20/2018; 12/09/2020				
NYU Langone Hospitals	330214	02/14/2012	07/27/2022	NY
550 First Avenue	1			
New York, NY 10016	1			
	1			
Other information:	1			
Joint Commission ID # 5820	1			
	1			
Previous Re-certification	1			
Dates: 02/14/2012;	1			
01/14/2014; 03/08/2016;	1			
03/27/2018; 8/26/2020				
The Johns Hopkins Hospital	210009	12/11/2007	06/15/2022	MD
600 N. Wolfe Street				
Baltimore, MD 21287	1			
, ====:	1			

Other information:				
Joint Commission ID # 6252				
Previous Re-certification				
Dates:				
12/11/2007; 12/15/2009;				
11/29/2011; 12/03/2013;				
01/12/2016; 02/13/2018;				
10/24/2020				
FROM: Jackson Memorial	100022	10/22/2009	06/22/2022	FL
Hospital				
TO: Public Health Trust of				
Dade County Florida dba				
Jackson Memorial Hospital				
1611 Northwest 12th Avenue				
Miami, FL 33136-1094				
Other information:				
Joint Commission ID # 6850				
Previous Re-certification				
Dates:				
10/22/2009; 10/21/2011;				
11/06/2013; 12/08/2015;				
12/08/2017; 3/3/2020				
Christ Hospital	360163	02/17/2012	07/09/2022	OH
2139 Auburn Avenue				
Cincinnati, OH 45219				
Other information:				
Joint commission ID #: 6987				
Previous Re-certification				
Dates:				
02/17/2012; 02/20/2014;				
04/05/2016; 03/20/2018;				
2/26/21				
MedStar Washington Hospital	090011	04/22/2008	07/08/2022	DC
Center				
110 Irving St, NW				
Washington, DC 20010				
Other information:				
Joint Commission ID # 6308				
Previous Re-certification				
Dates: 04/22/2008;				
04/06/2010; 03/23/2012;				
03/04/2014; 05/03/2016;				
05/22/2018; 12/17/2020				
Penn State Milton S. Hershey	390256	04/01/2008	06/30/2022	PA
Medical Center				
500 University Drive				
Hershey, PA 17033				
Joint Commission ID # 6075				
Previous Re-certification				
Dates: 04/01/2008;				
03/24/2010; 03/16/2012;				
, 05/10/2012,	1	I .		L

04/08/2014; 06/07/2016; 05/22/2018; 9/11/2020				
University of Texas Medical	450018	01/31/2012	06/08/2022	TX
Branch				
301 University Boulevard Galveston, TX 77555-0518				
Garreston, 171 / 7555 0510				
Other information:				
Joint commission ID #: 9058 Previous Re-certification				
Dates: 01/31/2012;				
01/28/2014; 02/23/2016;				
01/30/2018; 10/08/2020 Abington Memorial Hospital	390231	06/28/2012	07/16/2022	PA
1200 Old York Road	370231	00/20/2012	07/10/2022	111
Abington, PA 19001				
Other information:				
Joint commission ID #: 6013				
Previous Re-certification				
Dates:				
06/28/2012; 06/03/2014;				
06/28/2016; 05/22/2018	510001	07/26/2018	08/17/2022	WV
West Virginia University Hospitals, Inc.	310001	07/20/2018	08/17/2022	W V
One Medical Center Drive				
Morgantown, WV 26506				
Other information:				
Joint Commission ID # 6444				
Previous Re-certification Dates: 07-26-2018; 02-25-2021				
Medical University of South	420004	09/23/2010	07/21/2022	SC
Carolina Medical Center				
169 Ashley Avenue Charleston, SC 29425				
, and the second				
Other information:				
Joint Commission ID # 6584 Previous Re-certification				
Dates:				
09/23/2010; 09/07/2012; 08/05/2014; 09/13/2016;				
09/26/2018; 03/24/2021				
Scott & White Memorial	450054	12/07/2011	07/02/2022	TX
Hospital 2401 S 31st St				
Temple, TX 76508				
-				
Other information: Joint commission ID #: 9241				
Previous Re-certification				
Dates:				
12/07/2011; 12/03/2013; 01/12/2016; 12/19/2017;				
03/05/2020				
Carolinas Medical Center	340113	05/11/2010	08/03/2022	NC

1000 Divitha Davilariand	1			
1000 Blythe Boulevard				
Charlotte, NC 28232				
04 : 6 4:				
Other information:				
Joint Commission ID # 6480				
Previous Re-certification				
Dates:				
05/11/2010; 05/11/2012;				
04/22/2014; 04/12/2016;				
04/24/2018; 12/17/2020				
Saint Luke's Hospital of	260138	06/15/2010	08/05/2022	MO
Kansas City				
4401 Wornall Road				
Kansas City, MO 64111				
Other information:				
Joint Commission ID # 8351				
Previous Re-certification				
Dates:				
06/15/2010; 06/06/2012;				
05/06/2014; 06/21/2016;				
05/08/2018; 02/06/2021				
The University of Kansas	170040	03/08/2016	07/20/2022	KS
Hospital Authority				
4000 Cambridge Street				
Kansas City, KS 66160				
Tailous City, 150 00100				
Other information:				
Joint Commission ID # 8567				
Previous Re-certification				
Dates:				
03/08/2016; 03/06/2018				
03/06/2010; 03/00/2016	I			

Addendum XIII: Lung Volume Reduction Surgery (LVRS) (July through September 2022)

Addendum XIII includes a listing of Medicare-approved facilities that are eligible to receive coverage for lung volume reduction surgery. Until May 17, 2007, facilities that participated in the National Emphysema Treatment Trial were also eligible to receive coverage. The following three types of facilities are eligible for reimbursement for Lung Volume Reduction Surgery (LVRS):

- National Emphysema Treatment Trial (NETT) approved (Beginning 05/07/2007, these will no longer automatically qualify and can qualify only with the other programs);
- Credentialed by the Joint Commission (formerly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) under their Disease Specific Certification Program for LVRS; and
- Medicare approved for lung transplants.
 Only the first two types are in the list. For the purposes of this quarterly notice, we are providing only the specific updates to the list of

Medicare-approved facilities that meet our standards that have occurred in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Facility	Provider Number	Date of Certification	State
Ohio State University Hospitals 410 West Tenth Avenue, DN 168 Columbus, OH 43210	36-0085	10/29/2016	ОН
Other information: Joint Commission ID # 7029			
Recertification date: 08/28/2021 Previous Re-certification Dates: 12/15/2018			
Tammie Hayes, Director, LVRS, 614-293-3629			

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (July through September 2022)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage. For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (July through September 2022)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage. For questions or additional information, contact David Dolan, MBA (410-786-3365).

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